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Practitioner's Docket No. 480,006 (71025)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Marchionni et al.
Serial No.: 09/756,481
Filed: January 8, 2001
For: METHODS FOR TREATING NEUROLOGICAL INJURIES AND DISORDERS

Box Sequence
Assistant Commissioner for Patents
Washington, D.C. 20231

SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY, AND/OR AMENDMENT PERTAINING THERETO FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE

(check and complete this item, if applicable)

1. ☒ This replies to the Office Letter DATED October 18, 2001.

NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the serial number from the return post card or the attorney's docket number added.

☒ A copy of the Office Letter is enclosed.

IDENTIFICATION OF PERSON MAKING STATEMENT

2. I, Peter F. Corless
(type or print name of person signing below)

state the following:

ITEMS BEING SUBMITTED

3. Submitted herewith is/are

(check each item as applicable)

I, hereby certify that this correspondence is being deposited with the United States Postal Service first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231, on 12/13/01

Susan M. Dillon
(Date of Deposit)

- A. ☒ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. § 1.821(c) and 37 C.F.R. §§ 1.822 and 1.823.

- B. ☐ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. § 1.821(d).
- C. ☒ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. §§ 1.821(e) and 1.824.
- D. ☐ Please transfer to this application, in accordance with 37 C.F.R. § 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

In re application of:

Serial No.:

Filed:

For:

Group No.:

Examiner:

The Computer readable form(s) of applicant's other application corresponds to the "Sequence Identifier(s)" of the application as follows:

Computer Readable Form
(other application)

"Sequence Identifier"
(this application)

NOTE: "If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference maybe made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified." 37 C.F.R. 1.821(e).

- E. ☒ A statement that the content of each "Sequence Listing" submitted and each computer readable copy are the same, as required in 37 C.F.R. § 1.821(g).

☐ Because the statement is not made by a person registered to practice before the Office, the Statement is verified as required in 37 C.F.R. § 1.821(b).

- F. ☒ Because this submission is made in fulfilling the requirement under 37 C.F.R. § 1.821(g), a statement that the submission includes no new matter.

☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. § 1.821(g).

**STATEMENT THAT "SEQUENCE LISTING"
AND COMPUTER READABLE COPY ARE THE SAME**



AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER

4. I hereby state:

(complete applicable item A and/or B)

- A. ☒ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.
- B. ☒ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

STATUS

5. Applicant is

- ☐ a small entity. A statement:
☐ is attached.
☐ was already filed.
☒ other than a small entity.

EXTENSION OF TERM

6.

NOTE: "Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec.10, 1985 (1061 O.G. 34-35).

NOTE: See 37 C.F.R. 1.645 for extensions of time in interference proceedings and 37 C.F.R. 1.550(c) for extensions of time in reexamination proceedings.

7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply.

(complete (a) or (b) as applicable)

- (a) ☐ Applicant petitions for an extension of time under 37 C.F.R. 1.136 (fees: 37 C.F.R. 1.17(a)(1)-(4)) for the total number of months checked below:

| | | |
|-----------------------|------------------------------------|-------------------------|
| Extension (months) | Fee for other than small entity | Fee for small entity |
|-----------------------|------------------------------------|-------------------------|

| | | | |
|--------------------------|--------------|------------|-----------|
| <input type="checkbox"/> | one month | \$110.00 | \$ 55.00 |
| <input type="checkbox"/> | two months | \$390.00 | \$ 195.00 |
| <input type="checkbox"/> | three months | \$890.00 | \$ 445.00 |
| <input type="checkbox"/> | four months | \$1,390.00 | \$ 695.00 |

Fee \$ _____

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for _____ months has already been secured and the fee paid therefor of \$_____ is sufficient for extending the period for response.

Extension fee due with this request \$ 0.00

AND/OR

- (b) ☒ Applicant believes that no further extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

FEE PAYMENT

8. ☐ Attached is a check in the sum of \$ _____.

- ☐ Charge Account No. _____ the sum of \$ _____.

A duplicate of this transmittal is attached.

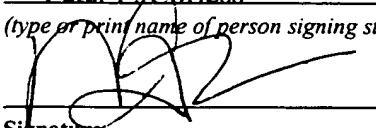
FEE DEFICIENCY

9.

NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.

10. ☒ If any additional extension and/or fee is required, charge Account No. 04-1105 .

SIGNATURE(s)

Peter F. Corless
(type or print name of person signing statement)

Signature

Dec. 13, 2001
Date

EDWARDS & ANGELL, LLP
P.O. Box 9169
P.O. Address of Signatory

Boston, MA 02209

(If applicable)

Tel. No.: (617) 439-4444
Reg. No. 33,860
Customer No.: 21874

- ☐ Inventor
☐ Assignee of complete interest
☐ Person authorized to sign on behalf of assignee
☒ Practitioner of record
☐ Filed under Rule 34(a)
☐ Registration No.
☐ Other
(specify identity of person signing)

(complete the following, if applicable)

(type name of assignee)

Address of assignee

Title of person authorized to sign on behalf of assignee

A "STATEMENT UNDER 37 C.F.R. 3.73(b)" is attached.

Assignment recorded in PTO on _____
Reel _____ Frame _____

Reg. No.

Tel. No.: ()

Customer No.:

#118272

SIGNATURE OF PRACTITIONER

(type or print name of practitioner)

P.O. Address



Docket No.47506 (71095)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Marchionni et al.
SERIAL NO.: 09/756,481
FILED: January 8, 2001
FOR: METHODS FOR TREATING NEUROLOGICAL INJURIES AND
DISORDERS

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS
WASHINGTON, DC 20231

SIR:

**STATEMENTS IN SUPPORT OF FILING AND
SUBMISSIONS IN ACCORDANCE WITH 37 CFR §§1.821 - 1.825**

In accordance with 37 CFR §§1.821 - 1.825, I hereby state that the content of the paper, computer-readable copies of the sequence listing submitted in accordance with 37 CFR §1.821(c) and (e), respectively, are the same.

Respectfully submitted,

Peter F. Corless (Reg. 33,860)
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02109
(617) 439-4444

Date: 12/13/01



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

| APPLICATION NUMBER | FILING/RECEIPT DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|---------------------|-----------------------|------------------------|
| 09/756,481 | 01/08/2001 | Mark Marchionni | 47506 |

Dike, Bronstein, Roberts & Cushman
Intellectual Property Practice Group
Edwards & Angell, LLP
P.O. Box 9169
Boston, MA 02209

RECEIVED

OCT 22 2001

EDWARDS & ANGELL LLP
DIKE, BRONSTEIN, ROBERTS & CUSHMAN

CONFIRMATION NO. 4213

FORMALITIES LETTER



OC00000006905492

Date Mailed: 10/18/2001

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase PatentIn Software, call (703) 306-2600
- For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

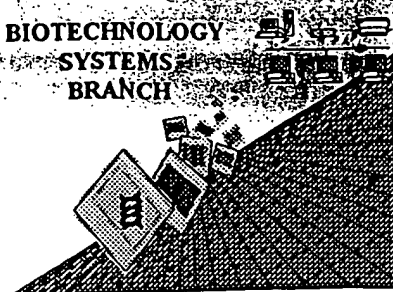
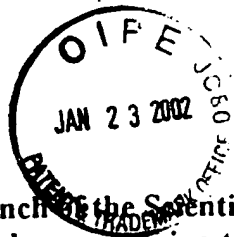
*A copy of this notice **MUST** be returned with the reply.*

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY

Sequence Listing
Edwards & Angell LLP
Dike, Bronstein, Roberts & Cushman
101 Federal St. Boston, MA 02110
Date Rec'd 10/22/01
Docketed For Nov 18 - Dec 18, 2001
By KRD
Approved 10/25/01

RAW SEQUENCE LISTING ERROR REPORT



The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/756,481

Source: O I P E

Date Processed by STIC: 08/16/2001

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW:

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 - 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.

Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:

<http://www.uspto.gov/web/offices/pac/checker>

Raw Sequence Listing Error Summary

ERROR DETECTED SUGGESTED CORRECTION

SERIAL NUMBER: 09/756,481

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 Wrapped Nucleics The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
- 1 Wrapped Aminos
- 2 Invalid Line Length The rules require that a line not exceed 72 characters in length. This includes white spaces.
- 3 Misaligned Amino The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
- 3 Numbering
- 4 Non-ASCII The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
- 5 Variable Length Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
- 6 PatentIn 2.0 A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) . Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 6 "bug"
- 7 Skipped Sequences Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
(i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
This sequence is intentionally skipped

Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
- 7 (OLD RULES)
- 8 Skipped Sequences Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 8 (NEW RULES)
- 9 Use of n's or Xaa's Use of n's and/or Xaa's have been detected in the Sequence Listing.
(NEW RULES) Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 10 Invalid <213> Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
- 10 Response
- 11 ✓ Use of <220> Sequence(s) all missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
- 12 PatentIn 2.0 Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
- 12 "bug"